REMARKS

The present invention relates to a method of treatment or prophylaxis of inflammatory bowel disease (IBD) comprising administration of a therapeutically effective amount of an inhibitor of CSF-1 activity. The inhibitor can be a nucleic acid as recited in claim 13, a small molecule as recited in claim 14, or an antibody or functionally active antibody fragment or derivative, as recited in claim 15.

September 8, 2008 Restriction Requirement

In response to the restriction requirement mailed September 3, 2008, applicants previously elected the Group 3 claims 12 and 15-25, wherein the inhibitor of CSF-1 activity is an antibody; claims 13 and 14 thus were withdrawn from consideration. The Office Action of September 3, 2008 also required restriction (a)between the two diseases of claims 21 and 22, (b)between the two secondary therapeutic agents of claims 24 and 25, and (c)between the two different antibodies of claims 19 and 20. In response to those requirements, applicants elected the inventions of claims 21, 24, and 19; accordingly, claims 22, 25, and 20 were withdrawn from consideration. Additionally, in response to an election of species requirement, applicants elected the humanized antibody recited in claim 16. Claim 16 was amended at that time to delete the non-elected antibody species.

Present Restriction Requirement

In the present action of December 10, 2008, at paragraph 4, the Office is requiring further election of species relating to use of an inhibitor of CSF-1 activity A) with no other anti-IBD agent or anti-cancer agent; or B) with another anti-IBD therapeutic agent; or C) with an anti-cancer agent; or D) with "more than one therapeutically active compound agents." As noted in paragraph 6 of the Action, applicants elected species A in a telephone interview on November 26, 2008. Applicant hereby affirms that election. The claims readable on this species are all claims except for claims 23-25.

With regard to paragraph 7 of the Action, the applicant notes with appreciation that claim 22 now is under consideration and is no longer withdrawn. The claim listing

presented herewith reflects that change. Further with regard to paragraph 7, the Examiner's statement that independent claim 12 is now withdrawn from consideration is respectfully traversed. Independent claim 12 is a generic or linking claim. Accordingly, pursuant to MPEP §§ 803.02 and 809, the applicants respectfully request the Office expand examination of the claims to the non-elected portion of the generic claims.

As stated in MPEP § 809,

> There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called 'linking' claims) which, if allowable, would require rejoinder of the otherwise divisible inventions. . . . The most common types of linking claims which, if allowable, act to prevent restriction between inventions that can otherwise be shown to be divisible, are (A) genus claims linking species claims . . . . The linking claims must be examined with, and thus are considered part of, the invention elected. When all claims directed to the elected invention are allowable, should any linking claim be allowable, the restriction requirement must be withdrawn. Any claims(s) directed to the non-elected invention(s), previously withdrawn from consideration, which depends from or requires all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability.

M.P.E.P. § 809 (emphasis added).

Claim16, reciting different types of antibodies and antibody fragments, ultimately depends from linking claim 12. In response to the prior election of species requirement, applicant had elected the species of humanized antibodies or antibody fragments, and had therefore amended that claim to delete the recitation of monoclonal, polyclonal, chimeric, or bispecific antibodies or fragments. Although the provisional election of the humanized species for purposes of examination is maintained, claim 16 is amended herein to include the non-elected species in the Markush group that were deleted in the last amendment. The proper procedure for examining such claims is described in M.P.E.P. § 803.02:

> A Markush-type claim may include independent and distinct inventions. … In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. … Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If

the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

* * *

On the other hand, should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *nonelected species,* the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The examination will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Applicants hereby reserve the right to prosecute the claims encompassed by any of the non-elected groups in future divisional applications.

Form of the Specification

With regard to paragraph 8 of the Office Action, the applicant believes that the title is adequately descriptive and that no change should be required. Nevertheless, for purposes of expediting prosecution in this case, the title of the application has been amended herein.

With regard to paragraph 9 of the Office Action, the Examiner has required that the specification be amended to insert section headings and sub-headings. The specification is amended herein to include those headings and sub-headings that are appropriate for the present application. Applicant is aware of no requirement in Title 37

of the Code of Federal Regulations that specifications must contain sub-headings for sections not actually included therein, followed by "Not Applicable."

With respect to paragraph 10 of the Office Action, the applicant has reviewed the application and believes that there are no registered or pending marks used therein that require either the ® or the ™ symbol. It is noted that on page 23 of the specification, the proper nouns are used as names of sources for the various materials employed in the Example, not as marks used to identify the materials themselves.

Rejection Under 35 USC 112, second paragraph

With regard to paragraph 12 of the Office Action, claim 15 has been amended to clarify the antibodies, fragments, and derivatives thereof that are contemplated within the scope of the invention. Support for the amendment is found in the specification, for example, at page 7, lines 8-13. It is respectfully submitted that this amendment is sufficient to overcome the rejection under 35 USC 112, second paragraph. In addition, claim 17 has been amended to properly recite the $F(ab')_2$ fragment.

Rejection Under 35 USC 112, first paragraph

With regard to paragraphs 13 and 14 of the Office action, claim 12 has been amended to delete the recitation of prophylaxis. It is respectfully submitted that this amendment is sufficient to overcome the rejection under 35 USC 112, first paragraph.

Rejection Under 35 USC 102

With respect to paragraphs 15-17 of the Office Action, the rejection of the pending claims under 35 USC 102(e) as anticipated by Bedian et al. (US2005/0059113) is respectfully traversed. The present application, having claims to a method of treating a particular disorder, is analogous to the application in the case of *Impax Laboratories, Inc. v. Aventis Pharmaceuticals, Inc.*, 545 F.3d 1312, 88 USPQ2d 1381 (Fed. Cir. 2008). In that case, the claims at issue related to a method of treating ALS comprising the step of administering a certain compound. The asserted prior art disclosed the claimed compound as one among many, disclosed ALS as one of several different disorders that

could be treated by administration of the disclosed compounds, and contained no working examples relating to ALS. In upholding the validity of the patent over that art, the Federal Circuit in *Impax* stated,

> "In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336, 86 USPQ2d 1609, (Fed. Cir. 2008) (citing *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1379, 82 USPQ2d 1643 (Fed. Cir. 2007)). In other words, the prior art must enable the claimed invention. *Minn. Mining & Mfg. Co. v. Chemque, Inc. (3M)*, 303 F.3d 1294, 1301, 64 USPQ2d 1270 (Fed. Cir. 2002). The 'undue experimentation' component of that equation examines (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400 (Fed. Cir. 1988)." 88 USPQ2d at 1383.

The district court had found that the prior art reference was not enabling as to the claimed invention under the *Wands* factors. This finding was upheld by the Federal Circuit. The court noted, *inter alia*, that ALS was one of many diseases listed in the prior art reference, and that the prior art reference included neither dosage guidelines nor working examples showing treatment of ALS, such that one skilled in the art would not know from the reference how to treat a person with ALS without undue experimentation. 88 USPQ2d at 1384.

For the same reasons, the Bedian et al. reference is not an enabling prior art reference as to the presently claimed method of treating IBD. In the Bedian et al. reference, IBD is one of over forty different and unrelated maladies that allegedly can be treated; these maladies range from diabetes to arthritis to asthma to malaria. Bedian et al. at [0249]. Nor does Bedian et al. provide any dosage guidelines, nor any working examples of how to treat any particular disease, much less IBD. In comparison, the present application provides working examples and data that amply demonstrate enablement of the presently claimed invention.

It is therefore respectfully submitted that the Bedian et al. reference is not enabling and therefore does not anticipate the claimed invention, and it is requested that this ground of rejection be withdrawn.

CONCLUSION

As all grounds of rejection have been overcome, a Notice of Allowance is requested. The Applicants invite the Examiner to contact the Applicants' undersigned representative at (312) 913-3362 if the Examiner believes that this would expedite prosecution of this application.

Respectfully submitted,

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